IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

| In re: LIPITOR ANTITRUST |) |
|-----------------------------|-----------------------------------|
| LITIGATION |) |
| |) MDL No. 2332 |
| THIS DOCUMENT RELATES TO: | |
| |) MASTER DOCKET NO.: 3:12-CV-2389 |
| ALL END-PAYOR CLASS ACTIONS |) (PGS/DEA) |
| | |
| | |
| | |
| |) |

ANSWER OF RANBAXY, INC., RANBAXY PHARMACEUTICALS, INC., AND RANBAXY LABORATORIES LTD. TO THIRD AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

Defendants Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., and Ranbaxy Laboratories, Ltd. (collectively "Ranbaxy")* hereby answer the allegations in the Third Amended Consolidated Class Action Complaint filed by End-Payor Class Plaintiffs (collectively "Plaintiffs") as follows:

I. INTRODUCTION**

1. Ranbaxy denies that Ranbaxy has engaged in any unlawful conduct or that Plaintiffs are entitled to any of the relief they seek. To the extent any response is required, Ranbaxy denies the remaining allegations in Paragraph 1.

^{*} Effective August 1, 2017, Ranbaxy Pharmaceuticals, Inc. merged with Sun Pharmaceutical Industries, Inc. Effective March 24, 2015, Ranbaxy Laboratories Ltd. merged with Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries Limited is the sole surviving entity of that merger.

^{**} Ranbaxy has included headings for organizational purposes only. Ranbaxy states that no response is required to the headings of the Complaint. To the extent any response is required to the headings of the Complaint, Ranbaxy denies each and every such heading.

- 2. The allegations contained in Paragraph 2 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 2.
- 3. The allegations contained in Paragraph 3 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 3.
- 4. The allegations contained in Paragraph 4 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 4.
 - 5. Ranbaxy denies the allegations contained in Paragraph 5.
- 6. The allegations contained in Paragraph 6 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 6.

Lipitor Patents and Warner-Lambert's Fraud on the PTO

- 7. Ranbaxy states that U.S. Patent No. 4,681,893 ("the '893 patent") speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 7, and therefore denies them.
- 8. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 8, and therefore denies them.
- 9. The allegations contained in Paragraph 9 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 9, and therefore denies them.

- 10. The allegations contained in Paragraph 10 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 10, and therefore denies them.
- 11. Ranbaxy admits on information and belief that U.S. Patent Number 5,273,995 ("the '995 patent") was issued and states that the patent speaks for itself. Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy also states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 11, and therefore denies them.

Sham Patent Infringement Litigation and Sham Citizen Petition

- 12. The allegations contained in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 12, and therefore denies them.
- 13. The allegations contained in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that it was the first to file an ANDA for generic Lipitor. Ranbaxy states that the docket and all filings and rulings related to the *Ranbaxy* litigation speak for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the docket, filings and rulings.
- 14. The allegations contained in Paragraph 14 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 14, and therefore denies them.

The Unlawful Reverse Payment, Market Allocation Agreement

- 15. The allegations contained in Paragraph 15 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 15, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy also states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the agreement and record.
- 16. The allegations contained in Paragraph 16 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 16, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy also states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the agreement and record.
- 17. The allegations contained in Paragraph 17 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 17, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy also states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the agreement and record.
- 18. The allegations contained in Paragraph 18 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 18, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy also states that the settlement agreement between

Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegations inconsistent with the agreement and record.

19. The allegations contained in Paragraph 19 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 19, and therefore denies them.

The Obstruction of Later Generic Entrants

- 20. The allegations contained in Paragraph 20 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 20. Ranbaxy further states that the settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any allegation or characterization inconsistent with the agreement and record.
- 21. The allegations contained in Paragraph 21 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 21.
- 22. The allegations contained in Paragraph 22 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 22. Ranbaxy further states that the settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any allegation or characterization inconsistent with the agreement and record.

Defendants' Actions Delayed Generic Competition for Many Months

23. The allegations contained in Paragraph 23 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 23, in particular to the extent they attempt to allege that Ranbaxy engaged

in any purported unlawful conduct, that plaintiffs were injured in any way, or that any purported injuries were caused by Ranbaxy's conduct.

II. THE PARTIES

- 24. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 24, and therefore denies them.
- 25. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 25, and therefore denies them.
- 26. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 26, and therefore denies them.
- 27. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 27, and therefore denies them.
- 28. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 28, and therefore denies them.

6

- 29. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 29, and therefore denies them.
- 30. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 30, and therefore denies them.
- 31. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 31, and therefore denies them.
- 32. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 32, and therefore denies them.
- 33. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 33, and therefore denies them.
- 34. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy.

Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 34, and therefore denies them.

- 35. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 35, and therefore denies them.
- 36. Ranbaxy denies that it engaged in any purported unlawful conduct alleged in the Complaint and denies that any Plaintiffs were injured as a result of any conduct by Ranbaxy. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations in Paragraph 36, and therefore denies them.
- 37. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 37, and therefore denies them.
- 38. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 38, and therefore denies them.
- 39. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 39, and therefore denies them.
 - 40. Paragraph 40 contains allegations to which no response is required.
 - 41. Paragraph 41 contains allegations to which no response is required.
 - 42. Ranbaxy denies the allegations contained in Paragraph 42.
- 43. Ranbaxy admits that Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business located at 600 College Road East, Princeton, New Jersey, 08540. Ranbaxy denies the remaining allegations contained in Paragraph 43.

- 44. Ranbaxy denies the allegations contained in Paragraph 44.
- 45. Paragraph 45 contains allegations to which no response is required.
- 46. The allegations contained in Paragraph 46 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies that it engaged in any purported unlawful conduct as alleged in Paragraph 46. Ranbaxy further denies all remaining allegations in Paragraph 46.

III. JURISDICTION AND VENUE

- 47. The allegations contained in Paragraph 47 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies that Plaintiffs are entitled to any relief. Ranbaxy admits this Court has subject matter jurisdiction over such action.
- 48. The allegations contained in Paragraph 48 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy Pharmaceuticals, Inc. and Ranbaxy, Inc. admit that they transact business within the District of New Jersey.** Ranbaxy denies all remaining allegations contained in Paragraph 48.

IV. LEGAL BACKGROUND

A. The Regulatory Structure for Approval of Generic Drugs and Substitution of Generics for Brand Name Drugs

49. The allegations contained in Paragraph 49 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation

9

^{**} Effective March 24, 2015, Ranbaxy Laboratories Ltd. merged with Sun Pharmaceutical Industries Ltd. Sun Pharmaceutical Industries Limited is the sole surviving entity of that merger.

inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 49.

- 50. The allegations contained in Paragraph 50 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 50.
- 51. The allegations contained in Paragraph 51 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 51.

1. The Hatch-Waxman Amendments

- 52. The allegations contained in Paragraph 52 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 52.
- 53. The allegations contained in Paragraph 53 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 53.

- 54. The allegations contained in Paragraph 54 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 54.
- 55. The allegations contained in Paragraph 55 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 55.

2. Paragraph IV Certifications

- 56. The allegations contained in Paragraph 56 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 56.
- 57. The allegations contained in Paragraph 57 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 57.
- 58. The allegations contained in Paragraph 58 and footnote 4 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization

or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 58 and footnote 4.

- 59. The allegations contained in Paragraph 59 and footnote 5 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 59 and footnote 5.
- 60. The allegations contained in Paragraph 60 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 60. Ranbaxy denies all remaining allegations contained in Paragraph 60.
- 61. The allegations contained in Paragraph 61 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 61. Ranbaxy denies all remaining allegations contained in Paragraph 61.

B. The Benefits of Generic Drugs

- 62. Ranbaxy states that pricing for generic drugs must be analyzed on a case-by-case basis. Ranbaxy denies all remaining allegations contained in Paragraph 62.
- 63. Ranbaxy states that the pertinent state statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the state statutes and regulations. Ranbaxy further states that pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 63, and therefore denies them.

- 64. Ranbaxy states that pricing for pharmaceutical drugs must be analyzed on a caseby-case basis. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 64, and therefore denies them.
- 65. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 65, and therefore denies them.
- 66. The allegations contained in Paragraph 66 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 66, and therefore denies them.

C. Brand Manufacturers Have Learned How to Exploit the Hatch-Waxman Regulatory Framework

- 67. The allegations contained in Paragraph 67 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy further states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 67, and therefore denies them.
- 68. The allegations contained in Paragraph 68 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy further states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 68, and therefore denies them.

- 69. The allegations contained in Paragraph 69 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 69. Ranbaxy denies all remaining allegations contained in Paragraph 69.
- 70. The allegations contained in Paragraph 70 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 70. Ranbaxy denies all remaining allegations contained in Paragraph 70.
- 71. The allegations contained in Paragraph 71 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 71, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy further states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 71. Ranbaxy denies all remaining allegations contained in Paragraph 71.
- 72. The allegations contained in Paragraph 72 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy further states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 72, and therefore denies them.

V. FACTUAL BACKGROUND

A. A Short Primer on Statins

- 73. Ranbaxy admits that Lipitor belongs to a class of drugs called statins, which lower cholesterol. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 73, and therefore denies them.
- 74. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 74, and therefore denies them.
- 75. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 75, and therefore denies them.
- 76. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 76, and therefore denies them.
- 77. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 77, and therefore denies them.
- 78. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 78, and therefore denies them.
- 79. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 79, and therefore denies them.
- 80. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 80, and therefore denies them.
- 81. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 81, and therefore denies them.
- 82. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 82, and therefore denies them.

B. The Chemistry of Enantiomers

- 83. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 83, and therefore denies them.
- 84. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 84, and therefore denies them.
- 85. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 85, and therefore denies them.
- 86. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 86, and therefore denies them.
- 87. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 87, and therefore denies them.
- 88. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 88, and therefore denies them.
- 89. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 89, and therefore denies them.
- 90. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 90, and therefore denies them.
- 91. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 91, and therefore denies them.
- 92. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 92, and therefore denies them.
- 93. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 93 and footnote 6, and therefore denies them.

C. Warner-Lambert Obtains the Original Lipitor Patent

- 94. Ranbaxy admits on information and belief that Warner-Lambert filed a patent application entitled "Trans-6-[2-(3-or 4-Carboxamido-Substituted Pyrrol-1-yl)alky]-4-Hydroprxypyran-2-one Inhibitors Of Cholesterol Synthesis." Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 94 and footnote 7, and therefore denies them.
- 95. The allegations contained in Paragraph 95 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 95. Ranbaxy denies all remaining allegations contained in Paragraph 95.

1. The Patent Specification for the Original Lipitor Patent

- 96. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 96, and therefore denies them.
- 97. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 97, and therefore denies them.
- 98. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 98, and therefore denies them.
- 99. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 99, and therefore denies them.
- 100. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 100, and therefore denies them.
- 101. Ranbaxy states that the '893 patent application speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the application. Ranbaxy states

that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 101, and therefore denies them.

Ranbaxy states that the '893 application and patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the application and patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 102, and therefore denies them.

2. The PTO Issues the Original Lipitor Patent

- 103. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 103, and therefore denies them.
- 104. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 104, and therefore denies them.
- 105. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 105, and therefore denies them.
- 106. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 106, and therefore denies them.

D. Warner-Lambert Fraudulently Obtains the '995 Enantiomer Patent

- 107. The allegations contained in Paragraph 107 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 107, and therefore denies them.
- 108. The allegations contained in Paragraph 108 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 108, and therefore denies them.
- 109. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 109, and therefore denies them.
- 110. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 110, and therefore denies them.
- 111. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 111, and therefore denies them.
- 112. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 112, and therefore denies them.
- 113. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 113, and therefore denies them.

1. The State of the Art: Knowledge of One Skilled in the Art of Statins in 1989

- 114. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 114, and therefore denies them.
- 115. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 115, and therefore denies them.

- 116. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 116, and therefore denies them.
- 117. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 117, and therefore denies them.
- 118. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 118, and therefore denies them.
- 119. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 119, and therefore denies them.
- 120. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 120, and therefore denies them.
- 121. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 121, and therefore denies them.
- 122. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 122, and therefore denies them.
- 123. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 123, and therefore denies them.
- 124. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 124, and therefore denies them.

2. Warner-Lambert Fraudulently Claims That the R-Trans Enantiomer is Ten Times More Active than the Racemate

125. The allegations contained in Paragraph 125 and footnote 8 state legal conclusions to which no response is required. Ranbaxy states that the referenced Application speaks for itself, and denies any characterization or allegation that is inconsistent with the application. To the extent

a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 125 and footnote 8, and therefore denies them.

- 126. The allegations contained in Paragraph 126 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 126, and therefore denies them.
- 127. The allegations contained in Paragraph 127 state legal conclusions to which no response is required. Ranbaxy states that the referenced Application speaks for itself, and denies any characterization or allegation that is inconsistent with the application. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 127, and therefore denies them.
- 128. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 128, and therefore denies them.
- 129. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 129 and footnote 9, and therefore denies them.
- 130. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 130, and therefore denies them.
- 131. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 131, and therefore denies them.

a. The CSI Table is Misleading and Affirmatively False

132. The allegations contained in Paragraph 132 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is

required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 132, and therefore denies them.

(1) The CSI Table is Misleading

- 133. The allegations contained in Paragraph 133 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 133, and therefore denies them.
- 134. The allegations contained in Paragraph 134 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 134, and therefore denies them.
- 135. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. Ranbaxy also states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 135, and therefore denies them.
- 136. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. Ranbaxy also states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 136, and therefore denies them.
- 137. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. Ranbaxy also states it is without

sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 137, and therefore denies them.

- 138. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 138, and therefore denies them.
- 139. The allegations contained in Paragraph 139 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 139, and therefore denies them.
- 140. The allegations contained in Paragraph 140 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 140, and therefore denies them.
- 141. The allegations contained in Paragraph 141 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 141, and therefore denies them.
- 142. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 142, and therefore denies them.

(2) The CSI Table is Affirmatively False

143. The allegations contained in Paragraph 143 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient

knowledge or information to admit or deny the allegations contained in Paragraph 143, and therefore denies them.

- 144. The allegations contained in Paragraph 144 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 144, and therefore denies them.
- 145. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 145, and therefore denies them.
- 146. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 146, and therefore denies them.
- 147. Ranbaxy states that the referenced Research Report speaks for itself, and denies any characterization or allegation that is inconsistent with that report. Ranbaxy further states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 147, and therefore denies them.
- 148. The allegations contained in Paragraph 148 state legal conclusions to which no response is required. Ranbaxy states that the referenced CSI Table speaks for itself, and denies any characterization or allegation that is inconsistent with the table. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 148, and therefore denies them.
- 149. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 149 and footnote 10, and therefore denies them.
- 150. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 150, and therefore denies them.

151. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 151, and therefore denies them.

3. The Initial Rejection: The PTO Determines the Claimed Compounds Are Anticipated by the '893 Patent

- 152. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 152, and therefore denies them.
- 153. The allegations contained in Paragraph 153 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 153.
- 154. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 154, and therefore denies them.
- 155. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 155, and therefore denies them.
- 156. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that

it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 156, and therefore denies them.

- 157. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 157, and therefore denies them.
 - 4. The Renewed Application: Warner-Lambert Submits the Roth Declaration, Again Falsely Claiming that the R-Trans Enantiomer is Ten Times More Active than the Racemate
- 158. The allegations contained in Paragraph 158 and footnote 11 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record and the declaration in the referenced proceedings speak for themselves, and denies any characterization or allegation that is inconsistent with that record and declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 158 and footnote 11, and therefore denies them.
- 159. The allegations contained in Paragraph 159 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record and the declaration in the referenced proceedings speak for themselves, and denies any characterization or allegation that is inconsistent with that record and declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 159, and therefore denies them.
 - a. Warner-Lambert Admits that the R-Trans Enantiomer is *Prima Facie* Obvious
- 160. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that

it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 160, and therefore denies them.

- 161. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 161 and footnote 12, and therefore denies them.
- Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 162, and therefore denies them.
- 163. Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 163 and footnote 13, and therefore denies them.

b. The Roth Declaration is Misleading and Affirmatively False

- 164. The allegations contained in Paragraph 164 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 164, and therefore denies them.
- 165. The allegations contained in Paragraph 165 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with

the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 165, and therefore denies them.

- 166. The allegations contained in Paragraph 166 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 166, and therefore denies them.
- 167. The allegations contained in Paragraph 167 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 167, and therefore denies them.
- 168. The allegations contained in Paragraph 168 and footnote 15 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 168 and footnote 15, and therefore denies them.
- 169. The allegations contained in Paragraph 169 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 169, and therefore denies them.

- 170. The allegations contained in Paragraph 170 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 170, and therefore denies them.
- 171. The allegations contained in Paragraph 171 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 171, and therefore denies them.
- 172. The allegations contained in Paragraph 172 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 172, and therefore denies them.
- 173. The allegations contained in Paragraph 173 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 173, and therefore denies them.
- 174. The allegations contained in Paragraph 174 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced declaration speaks for itself, and denies any characterization or allegation that is inconsistent with

the declaration. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 174, and therefore denies them.

5. The Final Rejection: The PTO Determines that the R-Trans Enantiomer is Anticipated

175. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 175, and therefore denies them.

6. The Appeal: the Patent Board of Appeals Determines that the R-Trans Enantiomer is *Prima Facie* Obvious

- 176. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 176, and therefore denies them.
- 177. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 177, and therefore denies them.
- 178. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 178, and therefore denies them.
- 179. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record.

Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 179, and therefore denies them.

180. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 180, and therefore denies them.

7. The '995 Patent Issues: PTO Relies on Biologic Data to Overcome Obviousness

- 181. Ranbaxy admits on information and belief that the '995 patent was issued and states that the patent speaks for itself. Ranbaxy denies any characterization or allegation that is inconsistent with the patent.
- 182. The allegations contained in Paragraph 182 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 182, and therefore denies them.
- 183. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 183, and therefore denies them.
- 184. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 184, and therefore denies them.

185. Ranbaxy states that the record related to the referenced patent proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 185, and therefore denies them.

E. Warner-Lambert Intended to Deceive the PTO

186. The allegations contained in Paragraph 186 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 186, and therefore denies them.

1. Warner-Lambert Manipulated the Existing Biologic Data to Show a Ten-Fold Increase in Activity and Intentionally Presented False Information

- 187. The allegations contained in Paragraph 187 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 187, and therefore denies them.
- 188. The allegations contained in Paragraph 188 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 188, and therefore denies them.
- 189. The allegations contained in Paragraph 189 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 189, and therefore denies them.

- 190. The allegations contained in Paragraph 190 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 190, and therefore denies them.
- 191. The allegations contained in Paragraph 191 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 191, and therefore denies them.
- 192. The allegations contained in Paragraph 192 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 192, and therefore denies them.
- 193. The allegations contained in Paragraph 193 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 193, and therefore denies them.
- 194. The allegations contained in Paragraph 194 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 194, and therefore denies them.

2. Warner-Lambert Admits that the Patent Specification Claims a Surprising Ten-Fold Increase in Activity

195. The allegations contained in Paragraph 195 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 195, and therefore denies them.

- 196. The allegations contained in Paragraph 196 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 196, and therefore denies them.
- 197. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 197, and therefore denies them.
- 198. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 198, and therefore denies them.

3. Warner-Lambert Intended for the PTO to Rely on the False Data and Claims

199. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 199, and therefore denies them.

F. FDA Approval: The FDA approves Lipitor and the Original Lipitor Patent Provides Years of Patent Protection

200. Ranbaxy admits on information and belief that the FDA approved Lipitor on December 17, 1996. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 200, and therefore denies them.

1. The Orange Book Listings for the '893 and '995 Patents

201. The allegations contained in Paragraph 201 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits on information and belief that Warner-Lambert listed both the '893 patent and the '995 patent in the FDA Orange Book. Ranbaxy further states that the '893 patent, '995 patent, and FDA Orange Book speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the

patents and Orange Book. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 201, and therefore denies them.

- 202. The allegations contained in Paragraph 202 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '893 patent, '995 patent, and FDA Orange Book speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents and Orange Book. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 202, and therefore denies them.
- 203. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 203, and therefore denies them.
- 204. The allegations contained in Paragraph 204 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that, upon information and belief, Warner-Lambert procured the '104 patent, '971 patent, and '156 patent. Ranbaxy further states that the '104, '971, and '156 patents speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 204, and therefore denies them.

2. The '893 Original Lipitor Patent Protected the Lipitor Franchise for Years

205. The allegations contained in Paragraph 205 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Warner-Lambert's application speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the application. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 205, and therefore denies them.

- 206. The allegations contained in Paragraph 206 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Warner-Lambert's application speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the application. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 206, and therefore denies them.
- 207. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 207, and therefore denies them.
- 208. The allegations contained in Paragraph 208 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Warner-Lambert's application speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the application. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 208, and therefore denies them.
- 209. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 209, and therefore denies them.
- 210. Ranbaxy states that the '893 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 210, and therefore denies them.

- 211. Ranbaxy states that the '995 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 211, and therefore denies them.
- 212. Ranbaxy states that the '893 Patent and '995 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with those patents. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 212, and therefore denies them.

3. The 1997 Launch of Lipitor

- 213. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 213, and therefore denies them.
- 214. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 214, and therefore denies them.

G. After launch, Warner-Lambert and Pfizer obtained and listed additional patents.

- 215. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 215, and therefore denies them.
- 216. The allegations contained in Paragraph 216 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that, upon information and belief, Warner-Lambert procured the '104 patent and '971 patent. Ranbaxy further states that the '104 patent and '971 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy states that it is without sufficient

knowledge or information to admit or deny the allegations contained in Paragraph 216, and therefore denies them.

- 217. The allegations contained in Paragraph 217 state a legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that, upon information and belief, Warner-Lambert procured the '156 patent in or around October of 1999. Ranbaxy further states that the '156 patent speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the patent. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 217, and therefore denies them.
- 218. The allegations contained in Paragraph 218 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits on information and belief that Warner-Lambert procured the '740 patent and '511 patent. Ranbaxy further states that the '740 patent and '511 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 218, and therefore denies them.
- 219. The allegations contained in Paragraph 219 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits on information and belief that Pfizer listed the '156 patent in the FDA Orange Book but not the '104 and '971 patents. Ranbaxy further states that the '104, '971, and '156 patents and the FDA Orange Book speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents and FDA Orange Book. Ranbaxy states that it is without sufficient knowledge or

information to admit or deny the allegations contained in Paragraph 219, and therefore denies them.

H. Pfizer Files Sham Litigation Against Ranbaxy Based on the '893 and '995 Patents.

- 220. Ranbaxy admits that it was the first to file an ANDA for generic Lipitor with a Paragraph IV certification. Ranbaxy's ANDA and Paragraph IV certification speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the filings.
- 221. The allegations contained in Paragraph 221 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy further admits that, on or about August 19, 2002, Ranbaxy filed ANDA 76-477. Ranbaxy admits that it was the first to file a substantially complete ANDA for generic atorvastatin calcium. Ranbaxy states that its ANDA and the pertinent regulations and statutes associated with that filing speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the content of the filing, regulations, and statutes. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 221, and therefore denies them.
- 222. Ranbaxy admits that it sent four Paragraph IV certification letters to Pfizer starting in late 2002. Ranbaxy states that the Paragraph IV certification letters speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the content of those certification letters. Ranbaxy denies all remaining allegations contained in Paragraph 222.
- 223. The allegations contained in Paragraph 223 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that Pfizer filed an action against Ranbaxy in the United States District Court for the District of Delaware. The complaint in that lawsuit and the pertinent regulations and statutes referenced in Paragraph 223 speaks for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the complaint or the pertinent regulations and statutes. Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 223, and therefore denies them.

- 224. Ranbaxy states that the docket and all filings and rulings related to the Ranbaxy litigation and the appeal in the United States Court of Appeals for the Federal Circuit speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the docket, filings and rulings.
- 225. Paragraph 225 contains allegations to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 225.
- 226. The allegations contained in Paragraph 226 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the docket and filings related to the referenced litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the docket and filings. Ranbaxy denies all remaining allegations contained in Paragraph 226.
- 227. The allegations contained in Paragraph 227 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies all remaining allegations contained in Paragraph 227.
- 228. The allegations contained in Paragraph 228 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record.

- 229. The allegations contained in Paragraph 229 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record.
- 230. Ranbaxy states that the record related to the referenced appeal to the Federal Circuit speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record.
- 231. The allegations contained in Paragraph 231 and footnote 18 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Federal Circuit's decision speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies all remaining allegations contained in Paragraph 231 and footnote 18.
- 232. The allegations contained in Paragraph 232 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 232, and therefore denies them.
- 233. The allegations contained in Paragraph 233 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies all remaining allegations contained in Paragraph 233.

- I. 2005: Pfizer files a baseless "citizen petition," intended to hinder ANDA approvals, which confirms its knowledge that Ranbaxy planned to use an amorphous formulation
- 234. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 234, and therefore denies them.
- 235. The allegations contained in Paragraph 235 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Ranbaxy litigation and the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the litigation record and the pertinent statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 235.
- 236. The allegations contained in Paragraph 236 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations in Paragraph 236, and therefore denies them.
- 237. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 237, and therefore denies them.
- 238. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 238, and therefore denies them.
- 239. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 239, and therefore denies them.
- 240. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 240, and therefore denies them.
- 241. The allegations contained in Paragraph 241 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 241, and therefore denies them.

- 242. The allegations contained in Paragraph 242 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 242, and therefore denies them.
- 243. The allegations contained in Paragraph 243 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 243, and therefore denies them.
- 244. The allegations contained in Paragraph 244 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 244, and therefore denies them.
- 245. The allegations contained in Paragraph 245 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 245, and therefore denies them.
- 246. The allegations contained in Paragraph 246 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 246, and therefore denies them.

- 247. The allegations contained in Paragraph 247 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 247, and therefore denies them.
- 248. The allegations contained in Paragraph 248 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 248, and therefore denies them.
- 249. The allegations contained in Paragraph 249 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 249, and therefore denies them.
- 250. The allegations contained in Paragraph 250 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 250, and therefore denies them.
- 251. The allegations contained in Paragraph 251 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 251, and therefore denies them.

- 252. The allegations contained in Paragraph 252 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 252, and therefore denies them.
- 253. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 253, and therefore denies them.
- 254. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 254, and therefore denies them.
- 255. Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 255.
- 256. Ranbaxy states that the pertinent statutes and regulations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the statutes and regulations. Ranbaxy denies all remaining allegations contained in Paragraph 256.
- 257. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 257, and therefore denies them.
- 258. Ranbaxy states that the Orange Book speaks for itself, and denies any characterization or allegation that is inconsistent with the Orange Book.
- 259. The allegations contained in Paragraph 259 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 259, and therefore denies them.

- 260. The allegations contained in Paragraph 260 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 260, and therefore denies them.
- 261. The allegations contained in Paragraph 261 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 261, and therefore denies them.
- 262. The allegations contained in Paragraph 262 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 262, and therefore denies them.
- 263. The allegations contained in Paragraph 263 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 263, and therefore denies them.
- 264. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 264, and therefore denies them.
- 265. The allegations contained in Paragraph 265 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 265, and therefore denies them.

J. Pfizer Files Sham Litigation Against Teva Based on the '995 Patent

- 266. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations that are contained in Paragraph 266, and therefore denies them.
- 267. The allegations contained in Paragraph 267 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 267, and therefore denies them.
- 268. The allegations contained in Paragraph 268 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 268, and therefore denies them.

K. Pfizer Files Sham Litigation Against Cobalt Based on the '995 Patent

- 269. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 269, and therefore denies them.
- 270. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 270, and therefore denies them.
- 271. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 271, and therefore denies them.
- 272. The allegations contained in Paragraph 272 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 272, and therefore denies them.

L. 2007-2008: Pfizer begins reissuance proceedings for the enantiomer patent.

- 273. The allegations contained in Paragraph 273 state a legal conclusion to which no response is required. Ranbaxy admits on information and belief that Pfizer sought reissuance of the '995 Patent, but denies any characterization or allegation that is inconsistent with the referenced reissuance application. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations that are contained in Paragraph 273, and therefore denies them.
- 274. The allegations contained in Paragraph 274 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 274, and therefore denies them.
- 275. The allegations contained in Paragraph 275 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 275, and therefore denies them.

1. The re-issuance proceeding show that the biologic data could not support a basis to issue the '995 patent.

276. The allegations contained in Paragraph 276 state a legal conclusion to which no response is required. Ranbaxy admits on information and belief that Pfizer sought reissuance of the '995 Patent, but denies any characterization or allegation that is inconsistent with the referenced reissuance application. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 276, and therefore denies them.

- 277. The allegations contained in Paragraph 277 state a legal conclusion to which no response is required. Ranbaxy states that the referenced Informational Disclosure Statement speaks for itself, and denies any characterization or allegation that is inconsistent with the referenced statement. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 277, and therefore denies them.
- 278. The allegations contained in Paragraph 278 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that it filed a protest before the PTO during Pfizer's reissuance proceedings, and denies any characterization or allegation that is inconsistent with the record of those proceedings. Ranbaxy denies all remaining allegations contained in Paragraph 278.
- 279. The allegations contained in Paragraph 279 state a legal conclusion to which no response is required. Ranbaxy states that the referenced Informational Disclosures Statement speaks for itself, and denies any characterization or allegation that is inconsistent with the referenced statement. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 279, and therefore denies them.
- 280. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 280, and therefore denies them.
- 281. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy

states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 281, and therefore denies them.

- 282. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 282, and therefore denies them.
- 283. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 283, and therefore denies them.
- 284. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 284, and therefore denies them.
- 285. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 285, and therefore denies them.

2. Pfizer Faced the Real Risk that its Application to Reissue the '995 Patent Would Be Denied.

- 286. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 286, and therefore denies them.
- 287. The allegations contained in Paragraph 287 state a legal conclusion to which no response is required. Ranbaxy states that the record in the referenced reissue proceedings speaks

for itself, and denies any characterization or allegation that is inconsistent with that record. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 287, and therefore denies them.

- 288. The allegations contained in Paragraph 288 state a legal conclusion to which no response is required. Ranbaxy states that the record in the referenced reissue proceedings speaks for itself, and denies any characterization or allegation that is inconsistent with that record. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 288, and therefore denies them.
- 289. Ranbaxy admits on information and belief that Pfizer listed the '893 Patent in the Orange Book. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 289, and therefore denies them.
- 290. The allegations contained in Paragraph 290 and footnote 19 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 290 and footnote 19, and therefore denies them.
- 291. The allegations contained in Paragraph 291 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 291 and therefore denies them.
- 292. The allegations contained in Paragraph 292 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 292.

M. The circumstances in early 2008 leading to the Ranbaxy Delay Agreement

293. The allegations contained in Paragraph 293 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 293.

1. The '893 patent could only bar generic entry until March of 2010, and Pfizer faced the risk that reissuance of the '995 Patent would be denied.

- 294. The allegations contained in Paragraph 294 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Ranbaxy litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 294.
- 295. The allegations contained in Paragraph 295 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 295.

2. The two Unasserted Stabilization Formulation Patents and the '156 Patent could not bar Ranbaxy's entry.

- 296. The allegations contained in Paragraph 296 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 296.
- 297. The allegations contained in Paragraph 297 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced patents speak for themselves, and denies any characterization or allegation that is inconsistent with those patents. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 297, and therefore denies them.

298. The allegations contained in Paragraph 298 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '156 patent and Ranbaxy's ANDA speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the '156 patent or Ranbaxy's ANDA. Ranbaxy denies the remaining allegations contained in Paragraph 298.

3. As to Lipitor, the two Process Patents would not apply to Ranbaxy's (nor likely to other generic companies') generic product

- 299. The allegations contained in Paragraph 299 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '511 patent and '740 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy denies the remaining allegations contained in Paragraph 299.
- 300. The allegations contained in Paragraph 300 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '511 patent and '740 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy denies the remaining allegations contained in Paragraph 300.
- 301. The allegations contained in Paragraph 301 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '511 patent and '740 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy denies the remaining allegations contained in Paragraph 301.
- 302. The allegations contained in Paragraph 302 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced

patents speaks for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy denies the remaining allegations contained in Paragraph 302.

- 303. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 303, and therefore denies them.
- 304. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 304, and therefore denies them.
- 305. The allegations contained in Paragraph 305 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 305.
- 306. The allegations contained in Paragraph 306 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that all patents and other related documents referred to in Paragraph 306 speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents and related documents. Ranbaxy denies the remaining allegations contained in Paragraph 306.
- 307. The allegations contained in Paragraph 307 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '511 patent and '740 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. Ranbaxy denies the remaining allegations contained in Paragraph 307.

4. Pfizer faced the risk that its citizen petition could be denied at any moment.

308. The allegations contained in Paragraph 308 state legal conclusions to which no response is required. Ranbaxy admits on information and belief that Pfizer's citizen petition relating to atorvastatin remained pending in early 2008. Ranbaxy states that the record relating to

Pfizer's citizen petition speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with that record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 308, and therefore denies them.

309. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 309, and therefore denies them.

5. As to Accupril, however, Pfizer had enormous leverage over Ranbaxy

- 310. The allegations contained in Paragraph 310 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the Accupril patent litigation between Ranbaxy and Pfizer speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 310.
- 311. The allegations contained in Paragraph 311 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 311.

N. Pfizer created the illusion of litigation to create the appearance of patent life beyond March of 2010.

- 312. Ranbaxy states that the litigation settlement agreement between Pfizer and Ranbaxy and the record in that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the record and agreement. Ranbaxy denies the remaining allegations contained in Paragraph 312.
- 313. Ranbaxy states that the litigation settlement agreement between Pfizer and Ranbaxy and the record in that patent litigation speak for themselves, and Ranbaxy denies any

characterization or allegation inconsistent with the record and agreement. Ranbaxy denies the remaining allegations contained in Paragraph 313.

- 314. The allegations contained in Paragraph 314 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that, on or about March 24, 2008, Pfizer filed a complaint in the United States District Court for the District of Delaware. Ranbaxy further states that Pfizer's Complaint in that action speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the complaint. Ranbaxy denies the remaining allegations contained in Paragraph 314.
- 315. The allegations contained in Paragraph 315 and footnote 20 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced patent litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 315 and footnote 20.
- 316. The allegations contained in Paragraph 316 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Pfizer's Complaint in the referenced action speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the complaint. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 316.
- 317. The allegations contained in Paragraph 317 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Pfizer's Complaint in the referenced action speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the complaint. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 317.

- 318. The allegations contained in Paragraph 318 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that Pfizer's Complaint in the referenced action, as well as the '511 patent and the '740 patent speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the referenced complaint or patents. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 318.
- 319. The allegations contained in Paragraph 319 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 319.
- 320. The allegations contained in Paragraph 320 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 320, and therefore denies them.
- 321. The allegations contained in Paragraph 321 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that record relating to the referenced patent litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 321.
- 322. The allegations contained in Paragraph 322 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that, on or about June 17, 2008, Pfizer and Ranbaxy entered into an agreement settling patent litigation between the parties. Ranbaxy denies the allegations contained in Paragraph 322 to the extent they attempt to

allege that Ranbaxy engaged in any purported unlawful conduct. Ranbaxy denies the remaining allegations contained in Paragraph 322.

- 323. Ranbaxy denies the allegations contained in Paragraph 323.
- 324. The allegations contained in Paragraph 324 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 324.
- 325. The allegations contained in Paragraph 325 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 325.

1. Pfizer's Financial Inducements to Ranbaxy

- 326. The allegations contained in Paragraph 326 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 326.
- 327. The allegations contained in Paragraph 327 and footnote 21 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 327 and footnote 21.

a. Pfizer's release of the *Accupril* liability was worth hundreds of millions of dollars.

- 328. The allegations contained in Paragraph 328 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that Ranbaxy and Teva entered into an agreement relating to the distribution of generic Accupril, but Ranbaxy states that the referenced agreement speaks for itself and denies any characterization or allegation inconsistent with that agreement. Ranbaxy denies the remaining allegations contained in Paragraph 328.
- 329. The allegations contained in Paragraph 329 state a legal conclusion to which no response is required. Ranbaxy states that the ANDAs referenced in Paragraph 329 speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with those ANDAs. To the extent a response is required, Ranbaxy admits that in or around December 2002 Ranbaxy filed an ANDA relating to Accupril and containing a Paragraph IV certification. Ranbaxy also admits that, upon information and belief, Teva filed the first ANDA relating to Accupril. Ranbaxy denies the remaining allegations contained in Paragraph 329.
- 330. The allegations contained in Paragraph 330 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced Accupril litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 330, and therefore denies them.
- 331. The allegations contained in Paragraph 331 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced Accupril litigation speaks for itself, and Ranbaxy denies any characterization or

allegation inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 331, and therefore denies them.

- 332. The allegations contained in Paragraph 332 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced Accupril litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 332, and therefore denies them.
- 333. The allegations contained in Paragraph 333 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced Accupril litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 333, and therefore denies them.
- 334. The allegations contained in Paragraph 334 and footnote 24 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy admits that Ranbaxy and Teva entered into an agreement relating to the distribution of generic Accupril, but Ranbaxy states that the referenced agreement speaks for itself and denies any characterization or allegation inconsistent with that agreement. Ranbaxy denies the remaining allegations contained in Paragraph 334.
- 335. The allegations contained in Paragraph 335 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced

agreement speaks for itself and denies any characterization or allegation inconsistent with that agreement. Ranbaxy denies the remaining allegations contained in Paragraph 335.

- 336. The allegations contained in Paragraph 336 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that the referenced ANDA and agreement speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with that ANDA and agreement. Ranbaxy admits that it obtained final FDA approval for its ANDA relating to Accupril in or about December 2004, and began marketing a generic Accupril product on or about December 16, 2004. Ranbaxy denies the remaining allegations contained in Paragraph 336.
- 337. The allegations contained in Paragraph 337 and footnote 25 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that referenced ANDA and the record of the referenced Accupril litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the ANDA and record. Ranbaxy denies the remaining allegations contained in Paragraph 337 and footnote 25.
- 338. The allegations contained in Paragraph 338 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 338.
- 339. The allegations contained in Paragraph 339 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy admits that Pfizer posted a \$200 million injunction bond.

Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 339, and therefore denies them.

- 340. The allegations contained in Paragraph 340 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the records related to the Accupril I and Accupril II litigations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the records. Ranbaxy denies the remaining allegations contained in Paragraph 340.
- 341. The allegations contained in Paragraph 341 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 341.
- 342. The allegations contained in Paragraph 342 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the records related to the Accupril I and Accupril II litigations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the records. Ranbaxy denies the remaining allegations contained in Paragraph 342 and footnotes 26 and 27.
- 343. The allegations contained in Paragraph 343 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 343.

- 344. The allegations contained in Paragraph 344 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril I litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 344 and footnote 28.
- 345. The allegations contained in Paragraph 345 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the records related to the Accupril I and Accupril II litigations speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the records. Ranbaxy denies the remaining allegations contained in Paragraph 345.
- 346. The allegations contained in Paragraph 346 and footnote 29 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril I litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 346 and footnote 29.
- 347. The allegations contained in Paragraph 347 and footnote 30 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 347 and footnote 30, and therefore denies them.
- 348. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 348 and footnote 31, and therefore denies them.
- 349. The allegations contained in Paragraph 349 and footnotes 32 and 33 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states

that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 349 footnotes 32 and 33.

- 350. The allegations contained in Paragraph 350 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced earnings conference call speaks for itself, and Ranbaxy denies any characterization and allegation inconsistent with the record. Ranbaxy denies the allegations contained in Paragraph 350.
- 351. The allegations contained in Paragraph 351 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced earnings conference call speaks for itself, and Ranbaxy denies any characterization and allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 351.
- 352. Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 352 and footnote 34, and therefore denies them.
- 353. The allegations contained in Paragraph 353 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 353.
- 354. The allegations contained in Paragraph 354 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the pertinent statutes and the record related to the Accupril II litigation speak for themselves, and Ranbaxy denies any

characterization or allegation inconsistent with the statutes or the record related to the Accupril II litigation. Ranbaxy denies the remaining allegations contained in Paragraph 354.

- 355. The allegations contained in Paragraph 355 and footnote 35 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegations inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 355 and footnote 35.
- 356. The allegations contained in Paragraph 356 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the Accupril II litigation speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the record. Ranbaxy denies the allegations contained in Paragraph 356.
 - b. Release of the *Accupril* liability for a token \$1 million payment is a large and unexplained reverse payment from Pfizer to Ranbaxy.
- 357. The allegations contained in Paragraph 357 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of the patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the allegations contained in Paragraph 357.
- 358. The allegations contained in Paragraph 358 and footnote 36 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the allegations contained in Paragraph 358 and footnote 36.

- 359. The allegations contained in Paragraph 359 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 359.
- 360. The allegations contained in Paragraph 360 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 360.
- 361. The allegations contained in Paragraph 361 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 361.

2. In exchange for Pfizer's payment, Ranbaxy agreed to delay its launch of Generic Lipitor and to bottleneck later would-be generics.

- 362. The allegations contained in Paragraph 362 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 362.
- 363. The allegations contained in Paragraph 363 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation

settlement agreement between Ranbaxy and Pfizer and the record of the patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 363.

- 364. The allegations contained in Paragraph 364 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of the patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 364.
- 365. The allegations contained in Paragraph 365 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of the patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies the remaining allegations contained in Paragraph 365.
 - 3. Absent the reverse payment agreement, Ranbaxy would have received FDA ANDA approval for generic Lipitor earlier.
 - 366. Ranbaxy denies the allegations contained in Paragraph 366.
- 367. The allegations contained in Paragraph 367 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Pfizer and Ranbaxy and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the agreement and record. Ranbaxy further states that the FDA's regulations, policies or procedures speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the FDA's regulations, policies or procedures. Ranbaxy denies the remaining allegations contained in Paragraph 367.

- 368. Ranbaxy denies the allegations contained in Paragraph 368.
- 369. The allegations in Paragraph 369 state legal conclusions, to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 369.
- 370. The allegations in Paragraph 370 state legal conclusions, to which no response is required. To the extent a response is required, Ranbaxy states that the record of the referenced citizen petition and the litigation settlement agreement between Pfizer and Ranbaxy speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the record and agreement. Ranbaxy denies the remaining allegations contained in Paragraph 370.

a. The longstanding FDA policy of prioritizing the review of ANDAs.

- 371. The allegations contained in Paragraph 371 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the FDA's regulations, policies or procedures speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the FDA's regulations, policies or procedures. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 371, and therefore denies them.
- 372. The allegations contained in Paragraph 372 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the FDA's regulations, policies or procedures speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the FDA's regulations, policies or procedures. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 372, and therefore denies them.

b. The FDA's review of Ranbaxy's ANDA for atorvastatin calcium.

- 373. The allegations contained in Paragraph 373 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that, on or about June 18, 2008, Ranbaxy publicly announced its agreement with Pfizer. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 373, and therefore denies them.
- 374. The allegations contained in Paragraph 374 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 374, and therefore denies them.

c. The tremendous pressure on the FDA to approve generic Lipitor.

- 375. The allegations contained in Paragraph 375 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 375.
- 376. The allegations in Paragraph 376 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced letter speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the letter. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 376, and therefore denies them.
- 377. The allegations contained in Paragraph 377 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 377.

4. Absent the reverse payment agreement, Ranbaxy would have launched generic Lipitor earlier.

- 378. The allegations contained in Paragraph 378 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 378.
 - 379. Ranbaxy denies the allegations contained in Paragraph 379.
 - 380. Ranbaxy denies the allegations contained in Paragraph 380.
- 381. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 381, and therefore denies them.
- 382. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 382, and therefore denies them.
 - 383. Ranbaxy denies the allegations contained in Paragraph 383.
 - 384. Ranbaxy denies the allegations contained in Paragraph 384.
- 385. The allegations contained in Paragraph 385 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the records of the referenced patent litigations and reissue proceedings speak for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the records. Ranbaxy denies the remaining allegations contained in Paragraph 385.
 - 386. Ranbaxy denies the allegations contained in Paragraph 386.
- 387. The allegations contained in Paragraph 387 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '995, '156, '511, '740, '104, and '971 patents referred to in Paragraph 387 speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents and applications. Ranbaxy denies the remaining allegations contained in Paragraph 387.

- 388. The allegations contained in Paragraph 388 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record related to the referenced ANDA speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with that record. Ranbaxy denies the remaining allegations contained in Paragraph 388.
- 389. The allegations contained in Paragraph 389 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 389.
- 390. The allegations contained in Paragraph 390 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 390.
- 391. The allegations contained in Paragraph 391 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 391.
- 392. The allegations contained in Paragraph 392 state legal conclusions to which no response is required. To the extent that that a response is required, Ranbaxy denies the allegations contained in Paragraph 392.
 - 393. Ranbaxy denies the allegations contained in Paragraph 393.
- 394. The allegations contained in Paragraph 394 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 394, and therefore denies them.

- 395. The allegations contained in Paragraph 395 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 395.
- 396. The allegations contained in Paragraph 396 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced ANDAs speaks for themselves, and Ranbaxy denies any characterization or allegation inconsistent with the ANDAs. Ranbaxy admits that it received final FDA approval for a simvastatin product on or about June 23, 2006. Ranbaxy denies the remaining allegations in Paragraph 396.
- 397. The allegations contained in Paragraph 397 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced ANDA speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the ANDA. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 397, and therefore denies them.
- 398. The allegations contained in Paragraph 398 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced agreement speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the agreement. Ranbaxy denies the allegations contained in Paragraph 398.
- 399. The allegations contained in Paragraph 399 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced agreement speaks for itself, and Ranbaxy denies any characterization or allegation inconsistent with the agreement. Ranbaxy denies the allegations contained in Paragraph 399.
 - 5. Absent the reverse payment agreement, Pfizer or a co-venture partner would have entered the Lipitor market with an authorized generic earlier.
 - 400. Ranbaxy denies the allegations contained in Paragraph 400.

- 401. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 401, and therefore denies them.
- 402. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 402, and therefore denies them.
- 403. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 403, and therefore denies them.
- 404. The allegations contained in Paragraph 404 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 404, and therefore denies them.
- 405. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 405, and therefore denies them.
- 406. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 406, and therefore denies them.
- 407. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 407, and therefore denies them.
- 408. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 408, and therefore denies them.

O. The Operation of the Ranbaxy Delay Agreement

409. The allegations contained in Paragraph 409 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Pfizer and Ranbaxy speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement. Ranbaxy denies the remaining allegations contained in Paragraph 409.

a. Ranbaxy withdraws its challenges to the re-issuance of an enantiomer patent.

- 410. The allegations contained in Paragraph 410 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the litigation settlement agreement between Pfizer and Ranbaxy speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement. Ranbaxy denies the remaining allegations contained in Paragraph 410.
- 411. Ranbaxy states that record in the referenced reissuance proceedings speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 411.
- 412. Ranbaxy states that record in the referenced reissuance proceedings speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy denies the remaining allegations contained in Paragraph 412.
- 413. The allegations contained in Paragraph 413 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the '667 patent and '995 patent and their related prosecution and/or re-issuance records speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents or records. Ranbaxy denies the remaining allegations contained in Paragraph 413.
- 414. The allegations contained in Paragraph 414 state legal conclusions to which no response is required. Ranbaxy states that the '667 patent and '995 patent speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 414.

415. The allegations contained in Paragraph 415 state a legal conclusion to which no response is required. Ranbaxy states that the '667 patent and '995 patent and their related prosecution and/or re-issuance records speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the patents or records. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 415.

b. The Ranbaxy Delay Agreement created a bottleneck preventing later ANDA filers from entering the market with generic Lipitor.

- 416. The allegations contained in Paragraph 416 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 416.
- 417. The allegations contained in Paragraph 417 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the settlement agreement between Pfizer and Ranbaxy and the pertinent statutes or regulations speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and the pertinent statutes or regulations. Ranbaxy denies the remaining allegations contained in Paragraph 417.
- 418. The allegations contained in Paragraph 418 state legal conclusions to which no response is required. Ranbaxy states that the pertinent statutes or regulations speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the pertinent statutes or regulations. To the extent a response is required, Ranbaxy denies the remaining allegations contained in Paragraph 418.
- 419. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 419, and therefore denies them.

420. The allegations contained in Paragraph 420 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 420, and therefore denies them.

(1) Apotex.

- 421. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 421, and therefore denies them.
- 422. The allegations contained in Paragraph 422 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 422, and therefore denies them.
- 423. The allegations contained in Paragraph 423 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 423, and therefore denies them.
- 424. The allegations contained in Paragraph 424 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or

information to admit or deny the allegations contained in Paragraph 424, and therefore denies them.

(2) Mylan

- 425. The allegations contained in Paragraph 425 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the referenced ANDA and the record in the referenced litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the ANDA or record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 425, and therefore denies them.
- 426. The allegations contained in Paragraph 426 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 426, and therefore denies them.
- 427. The allegations contained in Paragraph 427 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 427, and therefore denies them.
- 428. The allegations contained in Paragraph 428 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that

is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 428, and therefore denies them.

- 429. The allegations contained in Paragraph 429 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 429, and therefore denies them.
- 430. The allegations contained in Paragraph 430 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 430, and therefore denies them.
- 431. The allegations contained in Paragraph 431 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 431, and therefore denies them.

(3) Actavis.

432. The allegations contained in Paragraph 432 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the

referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 432, and therefore denies them.

- 433. The allegations contained in Paragraph 433 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 433, and therefore denies them.
- 434. The allegations contained in Paragraph 434 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the record in the referenced litigation speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with the record. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 434, and therefore denies them.
- 435. The allegations contained in Paragraph 435 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the records in the referenced litigations speaks for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the records. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 435, and therefore denies them.

c. The Ranbaxy Delay Agreement operated as an unlawful reverse payment agreement.

- 436. The allegations contained in Paragraph 436 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 436.
- 437. The allegations contained in Paragraph 437 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 437.
 - 438. Ranbaxy denies the allegations contained in Paragraph 438.

P. The PTO's Reissuance of the '995 Patent Does Not Absolve Warner-Lambert's Fraudulent Conduct or Otherwise Sanitize the '995 Patent

- 439. The allegations contained in Paragraph 439 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 439, and therefore denies them.
- 440. The allegations contained in Paragraph 440 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 440, and therefore denies them.
- 441. The allegations contained in Paragraph 441 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 441, and therefore denies them.
- 442. The allegations contained in Paragraph 442 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 442, and therefore denies them.

- 443. The allegations contained in Paragraph 443 and footnote 37 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 443 and footnote 37, and therefore denies them.
- 444. The allegations contained in Paragraph 444 and footnote 38 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 444 and footnote 38, and therefore denies them.
- 445. The allegations contained in Paragraph 445 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 445, and therefore denies them.
- 446. The allegations contained in Paragraph 446 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 446, and therefore denies them.

VI. EFFECT ON INTERSTATE COMMERCE

- 447. The allegations contained in Paragraph 447 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 447.
- 448. The allegations contained in Paragraph 448 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that it began marketing

generic Lipitor in the United States on or about November 30, 2011. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 448, and therefore denies them.

- 449. The allegations contained in Paragraph 449 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations in Paragraph 449.
 - 450. Ranbaxy denies the allegations contained in Paragraph 450.

VII. EFFECT ON INTRASTATE COMMERCE

- 451. The allegations contained in Paragraph 451 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy admits that it began marketing generic Lipitor in the United States on or about November 30, 2011. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 451, and therefore denies them.
- 452. The allegations contained in Paragraph 452 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations in Paragraph 452.
 - 453. Ranbaxy denies the allegations contained in Paragraph 453.

VIII. MONOPOLY POWER AND MARKET DEFINITION

- 454. The allegations contained in Paragraph 454 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 454.
- 455. The allegations contained in Paragraph 455 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 455, and therefore denies them.

- 456. The allegations contained in Paragraph 456 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 456, and therefore denies them.
- 457. The allegations contained in Paragraph 457 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 457.
- 458. The allegations contained in Paragraph 458 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 458.
- 459. The allegations contained in Paragraph 459 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 459, and therefore denies them.
- 460. The allegations contained in Paragraph 460 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 460.
- 461. The allegations contained in Paragraph 461 state legal conclusions to which no response is required. To the extent a response is required, denies the allegations contained in Paragraph 461.

- 462. The allegations contained in Paragraph 462 state legal conclusions to which no response is required. To the extent a response is required, denies the allegations contained in Paragraph 462.
- 463. The allegations contained in Paragraph 463 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 463.
- 464. The allegations contained in Paragraph 464 state a legal conclusion to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 464.

IX. MARKET EFFECTS

- 465. Ranbaxy denies the allegations contained in Paragraph 465.
- 466. The allegations contained in Paragraph 466 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that the FDA's regulations, rules and procedures speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the regulations, rules and procedures. Ranbaxy denies the allegations contained in Paragraph 466.
- 467. The allegations contained in Paragraph 467 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 467.
- 468. The allegations contained in Paragraph 468 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 468.
- 469. The allegations contained in Paragraph 469 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 469, and therefore denies them.

- 470. The allegations contained in Paragraph 470 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 470.
- 471. Ranbaxy admits that it has experience in the pharmaceutical industry but otherwise denies the allegations contained in Paragraph 471.
- 472. The allegations contained in Paragraph 472 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 472.
- 473. Ranbaxy states that issues relating to pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy denies the remaining allegations in Paragraph 473.
- 474. Ranbaxy states that issues relating to pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy denies the remaining allegations in Paragraph 474.
 - 475. Ranbaxy denies the allegations contained in Paragraph 475.
 - 476. Ranbaxy denies the allegations contained in Paragraph 476.
 - 477. Ranbaxy denies the allegations contained in Paragraph 477.

X. ANTITRUST IMPACT

478. The allegations contained in Paragraph 478 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 478, in particular to the extent they attempt to allege that Ranbaxy engaged in any purported unlawful conduct, that plaintiffs were injured in any way, or that any purported injuries were caused by Ranbaxy's conduct.

- 479. Ranbaxy denies the allegations contained in Paragraph 479 and denies that Plaintiffs are entitled to any of the relief they seek.
- 480. Ranbaxy states that issues relating to pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy denies the remaining allegations in paragraph 480.
- 481. Ranbaxy states that issues relating to pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy denies the remaining allegations in paragraph 481.
- 482. The allegations contained in Paragraph 482 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 482.
- 483. The allegations contained in Paragraph 483 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 483.
- 484. Ranbaxy states that issues relating to pricing for pharmaceutical drugs must be analyzed on a case-by-case basis. Ranbaxy denies the remaining allegations in Paragraph 484.

XI. CLASS ACTION ALLEGATIONS

- 485. The allegations contained in Paragraph 485 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 485, and therefore denies them.
- 486. The allegations contained in Paragraph 486 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 486, and therefore denies them.

- 487. The allegations contained in Paragraph 487 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 487, and therefore denies them.
- 488. The allegations contained in Paragraph 488 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 489.
 - 489. Ranbaxy denies the allegations in Paragraph 489.
 - 490. Ranbaxy denies the allegations in Paragraph 490.
- 491. The allegations contained in Paragraph 491 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 491 and, on that basis, denies those allegations.
 - 492. Ranbaxy denies the allegations in Paragraph 492.
- 493. The allegations contained in Paragraph 493 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations in Paragraph 493.
- 494. The allegations contained in Paragraph 494 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations in Paragraph 494.
- 495. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the remaining allegations contained in Paragraph 495, and therefore denies them.

XII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

For Monopolization Under State Law (Asserted against Pfizer)

- 496. Ranbaxy hereby incorporates each preceding and succeeding Paragraph as though fully set forth herein.
- 497. The allegations contained in Paragraph 497 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 497.
- 498. The allegations contained in Paragraph 498 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 498.
- 499. The allegations contained in Paragraph 499 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 499.
- 500. The allegations contained in Paragraph 500 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 500.
- 501. The allegations contained in Paragraph 501 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 501.
- 502. The allegations contained in Paragraph 502 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without

sufficient knowledge or information to admit or deny the allegations contained in Paragraph 502, and therefore denies them.

- 503. The allegations contained in Paragraph 503 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 503.
- 504. The allegations contained in Paragraph 504 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 504.
 - 505. Ranbaxy denies the allegations contained in Paragraph 505.
- 506. The allegations contained in Paragraph 506 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 506.
- 507. The allegations contained in Paragraph 507 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 507.
- 508. Ranbaxy denies the allegations contained in Paragraph 508 and denies that Plaintiffs are entitled to any of the relief they seek.
- 509. Ranbaxy denies the allegations contained in Paragraph 509 and denies that Plaintiffs are entitled to any of the relief they seek.
- 510. Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 510, and therefore denies them.

SECOND CLAIM FOR RELIEF

For Conspiracy to Monopolize Under State Law (Asserted Against All Defendants)

- 511. Ranbaxy hereby incorporates each preceding and succeeding Paragraph as though fully set forth herein.
- 512. The allegations contained in Paragraph 512 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy denies the allegations contained in Paragraph 512.
 - 513. Ranbaxy denies the allegations contained in Paragraph 513.
 - 514. Ranbaxy denies the allegations contained in Paragraph 514.
 - 515. Ranbaxy denies the allegations contained in Paragraph 515.
 - 516. Ranbaxy denies the allegations contained in Paragraph 516.
 - 517. Ranbaxy denies the allegations contained in Paragraph 517.
 - 518. Ranbaxy denies the allegations contained in Paragraph 518.
 - 519. Ranbaxy denies the allegations contained in Paragraph 519.
 - 520. Ranbaxy denies the allegations contained in Paragraph 520.
 - 521. Ranbaxy denies the allegations contained in Paragraph 521.
 - 522. Ranbaxy denies the allegations contained in Paragraph 522.
 - 523. Ranbaxy denies the allegations contained in Paragraph 523.
 - 524. Ranbaxy denies the allegations contained in Paragraph 524.
 - 525. Ranbaxy denies the allegations contained in Paragraph 525.
 - 526. Ranbaxy denies the allegations contained in Paragraph 526.

THIRD CLAIM FOR RELIEF

(Combination and Conspiracy in Restraint of Trade) (Asserted Against All Defendants)

- 527. Ranbaxy hereby incorporates each preceding and succeeding Paragraph as though fully set forth herein.
 - 528. Paragraph 528 contains allegations to which no response is required.
 - 529. Ranbaxy denies the allegations contained in Paragraph 529.
 - 530. Ranbaxy denies the allegations contained in Paragraph 530.
 - 531. Ranbaxy denies the allegations contained in Paragraph 531.
 - 532. Ranbaxy denies the allegations contained in Paragraph 532.
 - 533. Ranbaxy denies the allegations contained in Paragraph 533.
 - 534. Ranbaxy denies the allegations contained in Paragraph 534.
- 535. Ranbaxy states that the litigation settlement agreement between Ranbaxy and Pfizer and the record of that patent litigation speak for themselves, and Ranbaxy denies any characterization or allegation that is inconsistent with the agreement and record. Ranbaxy denies all remaining allegations contained in Paragraph 535.
 - 536. Ranbaxy denies the allegations contained in Paragraph 536.
 - 537. Ranbaxy denies the allegations contained in Paragraph 537.
 - 538. Ranbaxy denies the allegations contained in Paragraph 538.
 - 539. Ranbaxy denies the allegations contained in Paragraph 539.
 - 540. Ranbaxy denies the allegations contained in Paragraph 540.
 - 541. Ranbaxy denies the allegations contained in Paragraph 541.
 - 542. Ranbaxy denies the allegations contained in Paragraph 542.
 - 543. Ranbaxy denies the allegations contained in Paragraph 543.

- 544. Ranbaxy denies the allegations contained in Paragraph 544.
- 545. Ranbaxy denies the allegations contained in Paragraph 545 and denies that Plaintiffs are entitled to any of the relief they seek.

FOURTH CLAIM FOR RELIEF

Unfair or Deceptive Trade Practices (Asserted Against All Defendants)

- 546. Ranbaxy hereby incorporates each preceding and succeeding Paragraph as though fully set forth herein.
 - 547. Ranbaxy denies the allegations contained in Paragraph 547.
- 548. Ranbaxy denies the allegations contained in Paragraph 548 and denies that Plaintiffs are entitled to any of the relief they seek.
- 549. The allegations contained in Paragraph 549 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 549, and therefore denies them. Ranbaxy states that West Virginia Code § 46A-6-106(c) speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with that statute. Ranbaxy denies that the letter referenced in Paragraph 549, which was allegedly sent after Plaintiffs' initial complaint was filed, satisfied the pre-filing notice requirements of West Virginia Code § 46A-6-106(c) and reserves the right to seek dismissal of Plaintiffs' West Virginia Consumer Credit Protection Act claim.
- 550. The allegations contained in Paragraph 550 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 550, and therefore denies them. Ranbaxy states that Massachusetts General Laws Annotated Chapter

93A speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with that statute. Ranbaxy denies that the letter referenced in Paragraph 550, which was allegedly sent after Plaintiffs' initial complaint was filed, satisfied the pre-filing notice requirements of Massachusetts General Laws Annotated Chapter 93A and reserves the right to seek dismissal of Plaintiffs' Massachusetts Consumer Protection Act claim.

551. The allegations contained in Paragraph 551 state legal conclusions to which no response is required. To the extent a response is required, Ranbaxy states that it is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 551, and therefore denies them. Ranbaxy states that Massachusetts General Laws Annotated Chapter 93A speaks for itself, and Ranbaxy denies any characterization or allegation that is inconsistent with that statute. Ranbaxy denies that the letter referenced in Paragraph 551, which was allegedly sent after Plaintiffs' initial complaint was filed, satisfied the pre-filing notice requirements of Massachusetts General Laws Annotated Chapter 93A and reserves the right to seek dismissal of Plaintiffs' Massachusetts Consumer Protection Act claim.

XIII. DEMAND FOR JUDGMENT

No response is required to Plaintiff's demand for judgment. To the extent any response is required, Ranbaxy denies that Plaintiffs are entitled to any relief whatsoever.

XIV. JURY DEMAND

No response is required to Plaintiffs' demand for a jury trial.

AFFIRMATIVE DEFENSES

Without assuming any burdens that it would not otherwise bear, Ranbaxy asserts the following affirmative defenses:

First Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, for failure to state a claim upon which relief can be granted.

Second Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations.

Third Affirmative Defense

Plaintiffs have enjoyed the benefits of their purchase of the products which are the subject of the Complaint and are thereby barred from making the claims for relief set forth in the Complaint.

Fourth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered injury proximately caused by any conduct of Ranbaxy and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

Fifth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs failed to mitigate damages, if any, allegedly suffered as a result of the conduct they allege.

Sixth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered any actual injury or damage as a result of any conduct alleged as a basis of this lawsuit.

Seventh Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged damages, if any, are too speculative and uncertain.

Eighth Affirmative Defense

Any and all of Ranbaxy's actions alleged by Plaintiffs were lawful, justified, procompetitive, carried out in furtherance of Ranbaxy's legitimate business interests, and constitute *bona fide* business competition.

Ninth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, unclean hands, and/or laches.

Tenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs' alleged injuries and damages were not legally or proximately caused by any acts or omissions of Ranbaxy and/or were caused, if at all, by the conduct of Plaintiffs and/or third parties.

Eleventh Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have failed to plead fraudulent concealment with the requisite specificity.

Twelfth Affirmative Defense

To the extent Plaintiffs' claims would result in Ranbaxy paying damages to more than one claimant for the same alleged overcharge, they are barred because such multiple liability would violate rights guaranteed to Ranbaxy by the United States Constitution, including, without limitation, rights guaranteed under the Due Process Clause of the Fourteenth Amendment.

Thirteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because the acts or omissions of Ranbaxy did not substantially lessen competition in any properly defined market.

Fourteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Ranbaxy's alleged conduct was unilateral, reasonable, and based on independent, legitimate business and economic justifications.

Fifteenth Affirmative Defense

Plaintiffs' claims are barred based on Ranbaxy's immunity under the First Amendment for liability for claims asserted by Plaintiff.

Sixteenth Affirmative Defense

Plaintiffs' claims are barred by the immunity provided by the United States patent laws.

Seventeenth Affirmative Defense

Plaintiffs' claims are barred by the Noerr-Pennington doctrine and any other applicable privilege or immunity.

Eighteenth Affirmative Defense

Plaintiffs' claims are barred because some or all of the acts alleged against Ranbaxy are expressly permitted by state or federal statute, regulation, or other law.

Nineteenth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs and/or the putative class lack standing to assert its claims.

Twentieth Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because they are preempted by federal law.

Twenty-First Affirmative Defense

Plaintiffs' claims are barred, in whole or in part, because this action does not satisfy the requirements for certification as a class action pursuant to Fed. R. Civ. P. 23.

Twenty-Second Affirmative Defense

The *Trinko* doctrine and its progeny bar Plaintiffs' claims because any harm to competition complained of stems from the intricate, multi-tiered regulatory regime, which governs the production, sale, and manufacture of pharmaceutical products, including the FDCA, the Drug Price Competition and Patent Term Restoration Act of 1984 and related amendments, and FDA regulations.

Twenty-Third Affirmative Defense

Ranbaxy adopts by reference any additional, applicable defenses pleaded by the other defendants in this matter.

Ranbaxy reserves the right to amend this Answer or to assert other defenses as this action proceeds.

To the extent Ranbaxy has not stated a specific response to any allegation stated in the Complaint, Ranbaxy denies that allegation.

Based on all the foregoing as well as other grounds, Ranbaxy denies that Plaintiffs are entitled to any relief whatsoever.

Dated: October 4, 2018 Respectfully submitted,

SAIBER LLC

/s/ Arnold B. Calmann

Arnold B. Calmann Katherine A. Escanlar Jeffrey Soos SAIBER LLC One Gateway Center, Suite 1000 Newark, NJ 07102 abc@saiber.com

Jay P. Lefkowitz, P.C. KIRKLAND & ELLIS LLP 601 Lexington Avenue New York, NY 10022 (212) 446-4800

Karen N. Walker, P.C. Edwin John U Jonathan D. Janow 655 Fifteenth Street, N.W. Washington, D.C. 20005 (202) 879-500

Attorneys for Defendants Ranbaxy, Inc., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy Laboratories Ltd.